

(b) *Sponsor*. See Nos. 000009 and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations*. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water. Use of this product in excess of the approved dose may result in drug residues. Do not administer to pregnant cattle unless abortion is desired. Do not administer intravenously; this may potentiate adverse reactions.

(d) *Conditions of use*—(1) *Mares*—(i) *Amount*. Equivalent of 1 milligram of dinoprost per 100 pounds of body weight.

(ii) *Indications*. For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrus mares that have a corpus luteum.

(iii) *Limitations*. For use once as a single intramuscular injection. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount*. 5 milliliters (equivalent to 25 milligrams of dinoprost).

(ii)(a) *Indications*. For its luteolytic effect to control timing of estrus and ovulation in estrus cycling cattle that have a corpus luteum.

(b) *Limitations*. For use in beef cattle and nonlactating dairy heifers, as follows: Inject a dose of 5 milliliters intramuscularly either once or twice at a 10- to 12-day interval. With a single injection, cattle should be bred at the usual time relative to estrus. With the two injections, cattle can be bred after the second injection either at the usual time relative to detected estrus or at about 80 hours after the second injection. Estrus is expected to occur 1 to 5 days after injection if a corpus luteum was present. Cattle that do not become pregnant to breeding at estrus on days 1 to 5 after injection will be expected to return to estrus in about 18 to 24 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii)(a) *Indications*. For treatment of pyometra (chronic endometritis).

(b) *Limitations*. For intramuscular use as a single injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Nonlactating cattle*—(i) *Amount*. Five milliliters intramuscularly as a single injection.

(ii) *Indications*. For its abortifacient effect in nonlactating cattle.

(iii) *Limitations*. For intramuscular use only, during first 100 days of gestation. Cattle that abort will abort within 35 days after injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Lactating dairy cattle*—(i) *Amount*. Five milliliters intramuscularly as a single injection.

(ii) *Indications*. For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(iii) *Limitations*. Breed cattle as they are detected in estrus. If estrus has not been observed by 80 hours after injection, breed at 80 hours. If cattle return to estrus breed at the usual time relative to estrus. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Swine*—(i) *Amount*. 2 milliliters (equivalent to 10 milligrams of dinoprost).

(ii) *Indications*. For parturition induction in swine when injected within 3 days of normal predicted farrowing.

(iii) *Limitations*. For use in swine as follows: Inject a dose of 2 milliliters intramuscularly within 3 days of predicted farrowing. The response to treatment varies by individual animals with a mean interval from administration to parturition of approximately 30 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 4818, Feb. 2, 1976, as amended at 46 FR 13214, Feb. 20, 1981; 46 FR 39127, July 31, 1981; 48 FR 6331, Feb. 11, 1983; 48 FR 46023, Oct. 11, 1983; 49 FR 4373, Feb. 6, 1984; 64 FR 15685, Apr. 1, 1999]

§ 522.723 Diprenorphine hydrochloride injection.

(a) *Chemical name*. N-(Cyclopropylmethyl)-6,7,8,14-tetrahydro-7- α -(1-hydroxy - 1 - methylethyl) - 6,14 - endoethanonororipavine hydrochloride.

(b) *Specifications.* Each milliliter of diprenorphine hydrochloride injection, veterinary, contains 2 mg of diprenorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors.* See No. 053923 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(2) It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(3) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs and researchers.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 16241, Apr. 15, 1983; 60 FR 39847, Aug. 4, 1995; 64 FR 15684, Apr. 1, 1999]

§ 522.770 Doramectin.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of doramectin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

(iii) *Limitations.* Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle within 35 days of treatment. Not for use in fe-

male dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount.* 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations.* Administer as a single intramuscular injection. Do not slaughter swine within 24 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 53321, Oct. 11, 1996, as amended at 62 FR 44410, Aug. 21, 1997; 62 FR 62242, Nov. 21, 1997; 63 FR 68183, Dec. 10, 1998; 64 FR 13509, Mar. 19, 1999]

§ 522.775 Doxapram hydrochloride injection.

(a) *Specifications.* The drug is a sterile aqueous solution containing 20 milligrams doxapram hydrochloride per milliliter.

(b) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; to stimulate respiration following dystocia or caesarean section.

(2) For intravenous use in dogs and cats at a dose of 2½ to 5 milligrams of doxapram hydrochloride per pound of body weight in barbiturate anesthesia, 0.5 mg per lb. in gas anesthesia; for intravenous use in horses at 0.25 mg per lb. of body weight in barbiturate anesthesia, 0.2 mg per lb. in inhalation anesthesia, 0.25 mg per lb. with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.